REMARKS/ARGUMENTS

Claims 42-57 are currently being examined. Applicants have amended claims 42, 45, 49, 51, and 56 to more particularly and distinctly claim that which Applicants regard as their invention. No new matter has been introduced by this amendment.

Applicants request Rejoinder of claims 58-61. Under MPEP § 821.04, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Applicants assert that claims 42-57 are allowable and because the subject matter of claims 58-61 pertains to the same scope as the allowable claims in compliance with §821.04, these claims should be rejoined and allowed.

I. Rejection Under 35 U.S.C. § 112, First Paragraph

A. Claims 42-48 have been rejected as lacking written description for antibodies to Factor D that "completely inhibit complement activation". The Office admits that Figures 18 and 26 illustrate the complete inhibition of the alternative pathway. The Office further concludes that the specification only describes a single species of a genus and thus does not provide written description for claims broader than this single antibody species. Applicants respectfully traverse this rejection.

First, Applicants have amended claims 42, 45, and 51 to more particularly and distinctly claim that which Applicants regard as their invention. The Office acknowledges that the specification provides sufficient written description for complete inhibition of the alternative pathway and so this aspect of the rejection should be withdrawn.

As for the contention that the specification does not provide sufficient written description for antibodies that specifically bind to Factor D which completely inhibit alternative pathway complement activation at a molar ratio of about 1.5:1, Applicants disagree. In the guidelines provided by the Office regarding Written Description, Example 16 (See attached pages from the guidelines, pp. 59-60) specifically states that claims directed to any antibody that binds to a well characterized antigen meet the requirements under 35 U.S.C. § 112, first paragraph as providing written description because antibodies structurally well defined, antibody technology is well developed and mature, the level of skill in the art is high and advanced. Moreover, one of skill in the art would recognize that the spectrum of antibodies that bind to Factor D at a molar ratio of about 1.5:1 are implicitly disclosed and that mAb 166-32 is a sufficient representative species of this genus of antibodies. In view of these guidelines, Applicants submit that the specification provides sufficient written description for the entire genus of antibodies claimed to inform the skilled artisan that Applicants were in possession of the claims invention at the time the Application was filed. Therefore, Applicants request that the rejection be withdrawn.

B. Claims 42-48 have been rejected as lacking enablement for the genus of antibodies that completely inhibit complement activation at a molar ratio of 1.5:1 (antibody:Factor D). Applicants respectfully traverse this rejection as to the amended claims to a genus of antibodies that completely inhibit alternative pathway complement activation at a molar ratio of 1.5:1 (antibody:Factor D).

The Office admits that the specification enables antibodies that completely inhibit alternative pathway complement activation as illustrated by Figures 18 and 26, and e.g., Example 11.

Applicants have given extensive guidance as to how to test for antibodies that completely inhibit the alternative pathway complement activation and how to determine the molar ratio of antibody:Factor D necessary to achieve complete inhibition. As discussed above, antibody technology is a mature technology and is no longer unpredictable. Applicants have disclosed methods of making the claimed antibodies and a representative species. It would not require undue experimentation to practice the entire scope of the invention in view of the guidance provided by the specification, the skill in the art, the mature nature of the technology, the sufficient working example, and the lack of unpredictability in the antibody art. In view of the foregoing remarks, Applicants submit that the specification is enabling for the entire scope of the amended claims and the rejection should be withdrawn.

C. Claims 49-57 have been rejected because the Office alleges that Applicants' representative's statements are defective. Therefore, Applicants' representative hereby states that the deposit of HB12476 was made under the terms of the Budapest Treaty and, upon issuance of a patent from this application, all restrictions imposed upon the **deposit** will be irrevocably removed, except the requirement that the **Depository** notify the patentee of a request for the deposited material. In view of this statement, Applicants request that the rejection be withdrawn.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 49 and 51-57 have been rejected as being indefinite because it has been alleged that "166-32" does not adequately describe the monoclonal antibody. Applicants have amended the claims to clarify this issue and request that the rejection be withdrawn.

CONCLUSION

In view of the amendments and remarks presented above, Applicants submit that claims 42-57 are allowable and request rejoinder of claims 58-61.

Respectfully Submitted,

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Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.